REMARKS

Claims 1, 3-5, 7-14, 17, 31-55 and 57-96 were pending in the present application. By this amendment, claims 91-93 are cancelled. Upon entry of this amendment, claims 1, 3-5, 7-14, 17, 31-55 and 57-90, and 94-96 are currently pending and under consideration.

With respect to claim amendments and cancellation, Applicants have not dedicated or abandoned any unclaimed subject matter and moreover have not acquiesced to any rejections made by the Patent Office. Applicants expressly reserve the right to pursue prosecution of any presently excluded subject matter or claim embodiments in one or more future continuation and/or divisional application(s).

Withdrawn Rejections

Applicants acknowledge with appreciation withdrawal of the rejection of claims 1, 3-15, 17, 31-55, and 57-90 under 35 U.S.C. §112, second paragraph. Applicants acknowledge with appreciation the withdrawal of the rejection of claims 1, 3-5, 7-15, 17, 31-55, and 57-96 under 35 U.S.C. §112, first paragraph.

Claim Rejections – 35 USC § 103

Rejection based on Desai in view of Kunz further in view of Westesen

Claims 1, 3-5, 7-14, 17, 31-33, 38-41, 46-49, 54-55, 57-96 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Desai et al. ("Desai," 5,439,686) in view of Kunz et al. ("Kunz," 5,733,925) in further view of Westesen et al. ("Westesen," 6,197,349). Applicants respectfully traverse this rejection.

The claims of the present application are generally directed to methods of treating hyperplasia of non-cancerous cells in a blood vessel, and recite systemically administering an effective amount of a composition comprising an amorphous drug in nanoparticle form, coated with

a coating consisting essentially of protein in 30 minutes or less.[1] Applicants respectfully submit that the cited references, alone or in combination, do not teach or suggest the claimed invention. In finding claims of the present invention obvious over the cited references, the Examiner has failed to consider the claimed invention as a whole and failed to consider the cited references in their entirety.

Applicants maintain arguments already presented in conjunction with the rejections based on the cited references, which are incorporated into the present response. In the sections below, Applicants further address points raised by the Examiner in response to Applicants' arguments presented on January 12, 2009.

In response to Applicants' argument that Kunz does not teach or suggest the claimed invention or provide a motivation to combine the cited references, the Examiner emphasized that "the examiner is not attempting to incorporate Kunz's methodology into Desai's teachings nor is the examiner attempting to substitute Desai's particles with Kunz's," and that "[t]he only teaching lacking in Desai is the method of the composition for treating non-cancerous hyperplasia and an amorphous form. Thus, the examiner relies on Kunz's disclosure to cure this deficiency only." Page 7 of the Office Action. The Examiner reasoned that "Desai teaches the anti-neoplastic drugs such as taxol in protein shells and it is administered in less than 30 minutes....Desai also recognizes that taxol and its analogs disrupt microtubule function." *Id.* The Examiner concludes, "[t]hus, a skilled artisan would reasonably expect that Desai's taxol particles could be used to treat non-cancerous hyperplasia." Page 8 of the Office Action.

Applicants respectfully submit that that the Examiner's reasoning is misplaced and has failed to consider the cited references in their entirety. MPEP §2141.03.VI ("A prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention."). Further, the Examiner has failed to consider the claimed invention as a whole when applying the references. MPEP § 2141.02.I ("In determining the differences between the

[1] Independent claims 1, 9, and 17 recite aspects of the claimed treatment. For efficiency and conciseness, Applicants present arguments generally in terms of treating hyperplasia of non-cancerous cells in a blood vessel. These points apply to all claims.

prior art and the claims, the question under 35 U.S.C. 103 is not whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious.")(original emphasis).

The claims of the present application are generally directed to methods of treating hyperplasia of non-cancerous cells in a blood vessel, and recite systemically administering an effective amount of a composition comprising an amorphous drug in nanoparticle form, coated with a coating consisting essentially of protein in 30 minutes or less. The claims are based on the surprising finding that a nanoparticle composition comprising a drug in amorphous form, coated with a coating consisting essentially of protein, "when administered systemically, can markedly reduce the level of restenosis following balloon angioplasty and stenting," and "can markedly reduce the level of intimal hyperplasia or neointima formation following systemic administration." Page 8, lines 1-7 of the specification. The specification stated that transient exposure (such as that achieved by systemic administration, specifically, infusion over a period of 5 minutes) of a drug, namely, paclitaxel, in the form of nanoparticles coated with a coating consisting essentially of protein, "may alter the microtubular function of the smooth muscle cells for sustained periods, impairing their mobility and proliferation." Page 25, lines 18-20 of the specification; Examples 7 and 18.

Prior to the present invention, it was unpredictable to a person of ordinary skill in the art whether the method of the present invention would be effective in treating hyperplasia of non-cancerous cells in a blood vessel. Specifically, according to Kunz, an effective treatment of hyperplasia of non-cancerous cells in a blood vessel would entail adequate concentration of the drug at the target site. *See* Kunz at column 2, lines 37-46. One would not expect that transient exposure (i.e., systemic administration in 30 minutes or less) of an amorphous drug in nanoparticle form, coating with a coating consisting essentially of protein, would provide high enough local concentration of the drug at the desired target site to achieve beneficial effects for the treatment of hyperplasia of non-cancerous cells.

Further, hyperplasia of non-cancerous cells in the blood vessel takes place slowly. According to Kunz, it is important that the therapeutic drug be present over several weeks, perhaps

continuously, to produce beneficial effect. *See* Kunz at Column 2, lines 47-50. It was unpredictable to a person of ordinary skill in the art whether a composition comprising an amorphous drug in nanoparticle form, coated with a coating consisting essentially of protein, that is systemically administered over a period of 30 minutes or less would allow the drug be present at the target site long enough to produce beneficial effects, particularly in treating hyperplasia of non-cancerous cells in a blood vessel.

There is no teaching or suggestion in the cited references that the methods of the present invention would be effective in treating hyperplasia of non-cancerous cells in the blood vessel. Specifically, Desai discloses delivering pharmacologically active agents in protein-shell containing microparticle compositions that obviate the need for toxic organic solvents. Column 3, lines 29-34 and 45-58 of Desai. This allows substantially water insoluble pharmacologically active agents be administered in smaller volumes and at reduced administration time relative to those required in the prior art. Column 3, line 65 to column 4, line 2 of Desai. However, Desai does not teach the claimed methodology of treating hyperplasia of non-cancerous cells in a blood vessel. Nor does Desai suggest that systemically administering a composition comprising an amorphous drug in nanoparticle form, coated with a coating consisting essentially of protein in 30 minutes or less would be effective in treating hyperplasia of non-cancerous cells in a blood vessel. The teaching in Desai that its particles can be administered at a reduced time relative to those required in the prior art without incurring toxicity by no means suggests that such administration regime would provide high enough local drug concentration for a sustained period of time and allow effective treatment of hyperplasia of non-cancerous cells in the blood vessel.[2]

Kunz also does not provide teaching or suggestion to systemically administer a composition comprising an amorphous drug in nanoparticle form, coated with a coating consisting essentially of protein in 30 minutes or less for treating hyperplasia of non-cancerous cells in a blood vessel. Instead, Kunz discloses a targeted approach where the therapeutic agent is conjugated to a vascular smooth muscle cell binding protein or peptide, which allows the therapeutic agent be specifically

[2] As Applicants are addressing the basis of this aspect of the rejection in terms of systemically administering a nanoparticle composition in 30 minutes or less for the treatment of hyperplasia of non-cancerous cells in a blood vessel, Applicants need not and do not address the Examiner's statement that "Desai does not teach an amorphous drug."

targeted to vascular smooth muscle cells thus increasing the local concentration of the drug. Kunz also discloses "sustained release dosage forms," i.e., "a dosage form designed to release a therapeutic agent therefrom for a time period ranging from about 3 to about 21 days," or longer. Column 10, lines 7-11 of Kunz; *see also* column 3, line 63 to column 4, line 34 of Kunz. The sustained release dosage forms allow sustained release of therapeutic agents to target cells, such as vascular smooth muscle cells. Column 3, line 63 to column 4, line 3 of Kunz.

According to Kunz, an effective treatment of restenosis would entail: a) delivering a large number of molecules into the intracellular spaces between smooth muscle cells, b) directing an inhibitory drug into the proper intracellular compartment, and c) optimizing the association of the inhibitory drug with its intracellular target while minimizing intracellular redistribution of the drug, e.g., to neighboring cells. Column 2, lines 37-46 of Kunz. Kunz also teaches that, because smooth muscle cell proliferation takes place over several weeks, it would appear a priori that the inhibitory drug be administered over several weeks, perhaps continuously, to produce beneficial effects. Column 2, lines 47-50 of Kunz. The methodologies disclosed in Kunz were developed to specifically addressing these issues and considerations for treating hyperplasia of non-cancerous cells in a blood vessel.

Kunz is completely silent about systemically administering a composition comprising an amorphous drug in nanoparticle form, coated with a coating consisting essentially of protein in 30 minutes or less for treating hyperplasia of non-cancerous cells in a blood vessel. In fact, as discussed above, systemically administering a composition comprising an amorphous drug in nanoparticle form coated with a coating consisting essentially of protein, over an administration period of 30 minutes or less, would not be expected to address the issues and considerations highlighted in Kunz and would be contrary to the purpose of Kunz.

Accordingly, Applicants respectfully submit that the combined teachings of Kunz and Desai would not have suggested to those of ordinary skill in the art to arrive at the methods claimed in the present application. *See* MPEP § 2143.01.V ("If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification.").

The Examiner has responded to several arguments Applicants presented in the January 12, 2009 Response to Office Action by pointing to various disclosures in the cited references. Applicants respectfully submit that the Examiner has failed to consider the present invention as a whole when applying these references. *See* MPEP § 2141.02.I ("In determining the differences between the prior art and the claims, the question under 35 U.S.C. 103 is not whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious.")(original emphasis).

For example, in response to Applicants' argument that Example 8 of Desai does not disclose administration of a drug for treatment of hyperplasia of non-cancerous cells in a blood vessel, the Examiner states that Examiner 8 was relied on for "injecting the particles in a ten minute period, i.e., for the claimed method of administration." Page 10 of the Office Action. As discussed above, the teaching that Desai's particles can be systemically administered at a relatively reduced administration time by no means suggests that such administration would be effective in treating hyperplasia of non-cancerous cells in the blood vessel. The Examiner has not pointed to any teaching or suggestion in the cited references that would lead to the claimed method.

In response to Applicants' argument that Example 7 of Kunz would have led a person of ordinary skill in the art to believe that short-term administration of a non-targeted composition would be ineffective in treating hyperplasia of non-cancerous cells in a blood vessel, the Examiner states that "Kunz does not state that the free drugs are not effective" and that "Desai does not teach administration of a free drug." Pages 8-9 of the Office Action.

Applicants respectfully submit that the Examiner has failed to consider Kunz in its entirety when responding to Applicants' arguments. MPEP §2141.03.VI "[a] prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention." Specifically, Example 7 of Kunz evaluated the therapeutic efficacy of a therapeutic conjugate containing Roridin A and a vascular smooth muscle binding protein (VSMBP). Two therapeutic conjugates (VSMBP-RA2' and VSMBP-RA13') and one non-conjugated control therapeutic agent (free Roridin A or "RA") were administered intraarterially in about 3 minutes into a pig model. Histological examination revealed that the therapeutic conjugates resulted in marked

inhibition of intimal smooth muscle cell proliferation (a hypertrophy score of 1-3). Columns 4-9 of Table 2. The non-conjugated control therapeutic agent, on the other hand, was ineffective (a maximum hypertrophy scope of 4). Column 3 of Table 2. Based on the fact that the non-conjugated control therapeutic agent (free Roridin A or "RA"), when administered intraarterially in about three minutes, was ineffective in inhibiting cell proliferation (see column 3 of Table 2), a person of ordinary skill in the art would not have been led to believe that systemic administration of a composition that is not conjugated to a targeting moiety (such as compositions recited in the present claims), in a transient manner (i.e., in 30 minutes or less), would result in inhibition of cell proliferation and treatment of hyperplasia in a blood vessel. Applicants' arguments are based on the fact that the non-conjugated control therapeutic agent (free Roridin A or "RA") administered intraarterially in about three minutes was ineffective in inhibiting cell proliferation, rather than based on an inferior property of a free drug or a non-preferred embodiment in Kunz. The case law cited by the Examiner is thus inapplicable to the present case, and the Examiner's allegation that "Kunz does not state that the free drugs are not effective" and that "Desai does not teach administration of a free drug" misses the point of Applicants' argument.

The Examiner further states that "Kunz is not limited to only conjugated drugs" and points to column 15, lines 40-45 of Kunz for support. Page 9 of the Office Action. Applicants respectfully submit that column 15, lines 40-45 of Kunz provides "sustained release dosage forms," which as defined in the reference are "a dosage form designed to release a therapeutic agent therefrom for a time period ranging from about 3 to about 21 days.," or longer. Column 10, lines 7-11 of Kunz. The Examiner has not pointed to any teaching or suggestion in Kunz that would have led one of ordinary skill in the art to believe that that systemically administering a composition comprising an amorphous drug in nanoparticle form, coated with a coating consisting essentially of protein, in 30 minutes or less would be effective in treating hyperplasia of non-cancerous cells in a blood vessel.

Westesen does not cure the deficiency of Desai and Kunz discussed above. Specifically, Westesen is cited as allegedly teaching that use of an amorphous form of a poorly water soluble drug to provide better solubility and bioavailability of the poorly water soluble drug than utilizing a crystalline form. Westensen is completely silent about treatment of hyperplasia of non-cancerous

cells in a blood vessel. One of ordinary skill in the art reading Westesen would not expect that systemically administering a composition comprising an amorphous drug in nanoparticle form, coated with a coating consisting essentially of protein, in 30 minutes or less would be effective in treating hyperplasia of non-cancerous cells in a blood vessel.

Contrary to the expectation of an ordinary skill in art based on the teaching of the prior art, the methods of the present application produce unexpected beneficial effects. Applicants respectfully direct the Examiner's attention to *Exhibit* 1 submitted in the response to Office Action dated January 12, 2009 (attached hereto again for convenience), which provides evidence that a single dose of a composition comprising nanoparticles of paclitaxel coated with albumin (Nab-paclitaxel) administered intravenously was effective in inhibiting restenosis.

Accordingly, Applicants respectfully submit that Desai, Kunz, and Westesen, alone or in combination, do not render the claims obvious. Applicants respectfully request that the rejection under 35 U.S.C. § 103(a) be withdrawn.

Rejection based on Desai in view of Hunter further in view of Westesen

Claims 1, 3-5, 7-14, 17, 31-36, 38-43, 46-51, 54-55, 57-96 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Desai et al. ("Desai," 5,439,686) in view of Hunter et al. ("Hunter." 5,716,981) in further view of Westesen et al. ("Westesen," 6,197,349). Applicants respectfully traverse this rejection.

Applicants respectfully submit that the cited references, alone or in combination, do not teach or suggest the claimed invention. In finding claims of the present invention obvious over the cited references, the Examiner has failed to consider the claimed invention as a whole and failed to consider the cited references in their entirety.

Applicants maintain arguments already presented in conjunction with the rejections based on the cited references, which are incorporated into the present response. In the sections below,

Applicants further address points raised by the Examiner in response to Applicants' arguments presented on January 12, 2009.

The Examiner acknowledges that Desai fails to teach "the instant methodology of treating non-cancerous cell proliferation in blood vessels," and relies on Hunter for "the teaching of use of paclitaxel in treating hyperplasia." In response to Applicants' argument that Hunter does not teach systemic administration of a composition in 30 minutes or less for treating hyperplasia of non-cancerous cells in a blood vessel, the Examiner emphasized that "Hunter is not limited to using stents .... Hunter describes the various routes of administration and choosing an appropriate route so as to achieve the desired release of a drug would have been within the scope of a skilled artisan." Page 15 of the Office Action.

Applicants respectfully submit that Hunter does not teach or suggest systemically administering an effective amount of a composition comprising an amorphous drug in nanoparticle form, coated with a coating consisting essentially of protein, in 30 minutes or less for the treatment of hyperplasia of non-cancerous cells in a blood vessel. Specifically, Hunter discloses antiangiogenic compositions suitable for the treatment of various diseases, including for example cancer, hypertrophic scars and keloids, proliferative diabetic retinopathy, rheumatoid arthritis, psoriasis, stenosis, and other diseases. Although Hunter provides a general statement that the antiangiogenic compositions disclosed therein may be prepared for administration by different routes, including for example intravenous administration, it provides no guidance for choosing the claimed administration regime for treating hyperplasia of non-cancerous cells in a blood vessel. Further, given the special issues and considerations discussed above for treating hyperplasia of non-cancerous cells in a blood vessel, one of ordinary skill in the art would not have chosen the administration method recited in the present claims for the purpose of treating hyperplasia of non-cancerous cells in a blood vessel, and would not have expected that such administration method would be effective based on the broad general teachings of Hunter.

Applicants further submit that claims of the present application require systemic administration of a composition in 30 minutes or less. The Examiner points to the general list of administration route at column 38, lines 1-10 of Hunter for teaching the systemic administration,

while still relying on Hunter's teaching of stent delivery for the limitation of "administration in 30 minutes or less." Page 18 of the Office Action ("It should be noted that insertion of the stent would meet the instant delivery time since the composition is delivered to the site in less than 30 minutes (the time it takes to insert a stent than 30 minutes)"). Applicants respectfully submit that, by piecing the disclosures together, the Examiner has failed to consider the reference as a whole.

Westesen does not cure the deficiency of Desai and Hunter. Specifically, Westensen is cited as allegedly teaching that use of an amorphous form of a poorly water soluble drug to prove better solubility and bioavailability of the poorly water soluble drug than utilizing a crystalline form. Westensen is completely silent about treatment of hyperplasia of non-cancerous cells in a blood vessel. One of ordinary skill in the art reading Westesen would not expect that systemically administering a composition comprising an amorphous drug in nanoparticle form, coated with a coating consisting essentially of protein, in 30 minutes or less would be effective in treating hyperplasia of non-cancerous cells in a blood vessel.

Accordingly, Applicants respectfully submit that Desai, Hunter, and Westesen, alone or in combination, do not render the claims obvious. Applicants respectfully request that the rejection be withdrawn.

Rejection based on Desai in view of Kunz or Hunter further in view of Westesen further in view of Gregory

Claims 36-37, 44-45 and 52-53 are rejected under U.S.C. § 103(a) as allegedly being unpatentable over Desai et al. ("Desai," 5,439,686) in view of Kunz et al. ("Kunz," 5,773,925) or Hunter ("Hunter," 5,716,981) respectively in view of Westesen et al. ("Westesen," 6,197,349) in further view of Gregory ("Gregory," Transplantation, vol. 59, pp. 655-661, 1995). Applicants respectfully traverse this rejection.

Applicants maintain arguments already presented in conjunction with the rejections based on the cited references, which are incorporated into the present response.

Desai, Kunz, Hunter, and Westesen are discussed above. As discussed above, these references, alone or in combination, do not render the claims of the present invention obvious.

Gregory is cited as allegedly teaching that rapamycin is an immunosuppressant which has an antiproliferative action that is useful in the treatment of arterial thickening after injury such as angioplasty. Gregory does not cure the deficiencies discussed above.

Accordingly, Applicants respectfully submit that the cited references do not render claims of the present application obvious and respectfully request that the 35 USC 103 rejection be withdrawn.

Rejection based on Hunter by itself or in view of Yapel further in view of Kunz and Westesen

Claims 1,3-5, 7-14, 17, 31-33, 34-35, 38-41, 42-43, 46-49, 50-51 54-55, 57-96 are rejected under 35 U.S.C. §103(a) as being unpatentable over Hunter et al. ("Hunter," 5,716,981) by itself or in view of Yapel ("Yapel," 4,147,767) in further view of Kunz et al. ("Kunz," 5,733,925) and Westesen et al. (Westesen," 6,197,349). Applicants respectfully traverse this rejection.

Applicants maintain arguments already presented in conjunction with rejections based on the cited references, which are incorporated into the present response. In the sections below, Applicants further address points raised by the Examiner in response to Applicants' arguments presented on January 12, 2009.

In response to Applicants' argument that Hunter does not teach or suggest that systemically administering an amorphous drug in nanoparticle form, coating with a coating consisting essentially of protein in 30 minutes or less would be effective in treating hyperplasia of non-cancerous cells in a blood vessel, the Examiner states that "Hunter is taught for the use of paclitaxel in treating hyperplasia and the teaching of a nanoparticle of protein shell comprising the drug comes from Desai." Page 22 of the Office Action.

Applicants respectfully note that the rejection in this section is not based on Desai. The Examiner thus has also failed to establish which reference other than Desai provides the teaching of a "drug in nanoparticle form, coated with a coating consisting essentially of protein."

Further, as discussed above, none of Hunter, Kunz, Desai, or Westesen teaches or suggests systemically administering a therapeutic agent in nanoparticle form, coated with a coating consisting essentially of protein in 30 minutes or less.

Desai is completely silent about systemically administering a composition comprising an amorphous drug in nanoparticle form, coated with a coating consisting essentially of protein in 30 minutes or less. As discussed above, the teaching in Desai that its particles can be administered at a reduced time relative to those required in the prior art without incurring toxicity by no means suggests that such administration regime would provide high enough local drug concentration for a sustained period of time and allow effective treatment of hyperplasia of non-cancerous cells in the blood vessel.

Kunz is completely silent about systemically administering a composition comprising an amorphous drug in nanoparticle form, coated with a coating consisting essentially of protein in 30 minutes or less. As discussed above, systemically administering a composition comprising an amorphous drug in nanoparticle form coated with a coating consisting essentially of protein, over an administration period of 30 minutes or less, would not be expected to address the issues and considerations highlighted in Kunz and would defy the purpose of Kunz. Further, certain teaching in Kunz would have led a person of ordinary skill in the art to believe that short-term administration of a non-targeted composition would be ineffective in treating hyperplasia of non-cancerous cells in a blood vessel.

Hunter is completely silent about systemically administering a composition comprising an amorphous drug in nanoparticle form, coated with a coating consisting essentially of protein in 30 minutes or less. Given the special issues and considerations discussed above for treating hyperplasia of non-cancerous cells in a blood vessel, one of ordinary skill in the art would not have chosen the administration method recited in the present claims for the purpose of treating

hyperplasia of non-cancerous cells in a blood vessel, and would not have expected that such administration method would be effective based on the broad general teachings of Hunter.

Westensen is completely silent about treatment of hyperplasia of non-cancerous cells in a blood vessel. One of ordinary skill in the art reading Westesen would not expect that systemically administering a composition comprising an amorphous drug in nanoparticle form, coated with a coating consisting essentially of protein, in 30 minutes or less would be effective in treating hyperplasia of non-cancerous cells in a blood vessel.

Yapel does not cure the deficiencies discussed above. Specifically, Yapel is relied upon "to provide further motivation to utilize albumin." Yapel neither teaches a "drug in nanoparticle form, coated with a coating consisting of protein" nor teaches systemic administration of said drug in 30 minutes or less for treating hyperplasia of non-cancerous cells in the blood vessel.

Accordingly, Applicants respectfully submit that the cited references do not render claims of the present application obvious and respectfully request that the 35 USC § 103 rejection be withdrawn.

Rejection based on Hunter by itself or in view of Yapel in view of Kunz and Westesen further in view of Marx

Claims 36-37, 44-45, 52-53 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Hunter et al. ("Hunter," 5,716,981) by itself or in view of Yapel ("Yapel," 4,147,767) in view of Kunz et al. ("Kunz," 5,733,925) and Westesen et al. ("Westesen," 6,197,349) in further view of Marx ("Marx," Circ. Res. Vol. 76, pp. 412-417, 1995). Applicants respectfully traverse this rejection.

Applicants maintain arguments already presented in conjunction with rejections based on the cited references, which are incorporated into the present response.

As discussed above, Hunter, Yapel, Kunz, and Westesen, alone or in combination, do not render claims of the present application obvious. Marx is cited as allegedly teaching rapamycin as

an inhibitor of smooth muscle cells in the abnormal proliferation of restenosis. Marx does not cure the deficiencies discussed above.

Accordingly, Applicants respectfully submit that the cited references do not render claims of the present application obvious and request that the 25 USC §103 rejection be withdrawn.

Double Patenting

Claims 1, 3-5, 7-14, 17, 31-33, 38-41, 46-49, 54-55, 57-96 are provisionally rejected under obviousness-type double patenting over claims 1-2, 5-18 of 11/594,417. Claims 1, 3-14, 17, 31-33, 38-41, 46-49, 54-55, and 57-96 are provisionally rejected under obviousness-type double patenting over claims 1-7, 11-20, 44-45 of 11/359,286 in view of Hunter et al. and Westesen et al.

Applicants respectfully request that these provisional projections be held in abeyance until the Office has made a determination of otherwise allowable claims in the present application or in copending Application Nos. 11/594,417 and 11/359,286.

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 03-1952 referencing docket no. 638772000127. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Dated: October 14, 2009

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